
EXECUTIVE SUMMARY

Conference Executive Summary: Priority Education Messages on the Prevention and Treatment of Osteoporosis

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The FDA Special Topic Conference on Osteoporosis was designed to establish a baseline of reliable information on specific measures and interventions for preventing osteoporosis. The Osteoporosis Working Group, established by the FDA Advisory Group on Women's Health Issues to plan and implement this conference, recognized that there were inaccurate and conflicting messages directed to the public about osteoporosis prevention and treatment. Osteoporosis had become popularized as a disease condition, and the public was very receptive to learning more about osteoporosis, and what they could do to ward off the debilitating effects of this serious condition.

To meet the public need for accurate and timely information about the prevention of osteoporosis, the Osteoporosis Working Group recommended that the Special Topic Conference sponsored by FDA assemble experts in the various disciplines associated with the prevention of osteoporosis. These experts would establish a substantive base, identifying the limits of our knowledge about osteoporosis, and focus on the primary preventive interventions and education messages that could be drawn from this base of information. The target audience for this conference was the "front-line" health care providers: physicians, nurses, pharmacists, public health educators, health communicators, and health reporters, who consistently and systematically reach those women who are most at risk for this disease condition, and support them in their efforts to reduce this risk.

As evidenced by these proceedings, both nationally and internationally renowned experts presented a substantive scientific baseline of information about the prevention, diagnosis, and treatment of osteoporosis,

and what we can conclude from this baseline. The summaries of the panel moderators, which precede each session, provide an overview of the highlights of the complete panel presentation.

This Executive Summary is intended to consolidate the key prevention messages presented by the conference experts that should be incorporated into ongoing programs to inform and support younger, middle-aged, and older women in their efforts to minimize the risk of osteoporosis.

Bone Mass, Bone Loss Measurement

The Osteoporosis Working Group recognized that there is a proliferation of centers and clinics promoting osteoporosis screening directly to women. These ads—which are aired on television and radio, as well as published in newspapers and magazines—focus most often on identifying the candidate for osteoporosis, and promote the indiscriminate screening of any woman who decides to take advantage of the advertised service. This Working Group recognizes that such indiscriminate screening is of little value to the prevention and treatment of osteoporosis.

The FDA Osteoporosis Working Group recognized that there is considerable debate about bone measurement screening, and which modalities to use on whom. **The prevailing medical opinion is that bone mass and bone loss measurements *should not* be used to indiscriminately screen for osteoporosis.**

However, many experts recognize that there is a need to identify "fast bone losers" as early as possible to prevent further bone loss through needed interventions. Bone loss measurement can play a role in this process, as an informative measure to be used in determining the appropriateness of estrogen replacement therapy, to prevent osteoporosis.

The key education messages for bone mass, bone loss measurement are primarily directed towards *treatment* decisions.

- Menopause is a time when it is most important for physicians to determine whether or not a woman is a potential rapid bone loser. The white middle-aged woman reaching menopause is at the highest risk for osteoporosis. The doctor should base the identification of a rapid bone loser on such factors as family history, patient history, and high risk behaviors (e.g., smoking, diet, lack of exercise), as well as any clinical indicators of this disease condition.

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- If the information indicates that a woman is a rapid bone loser, she is a candidate for estrogen therapy to stop further bone loss. Women and their physicians should discuss this therapy, and agree on whether to initiate this treatment to prevent osteoporosis. In such cases, a bone loss analysis would not be necessary.
- If the information is inconclusive, the physician should consider a bone loss analysis consisting of the appropriate blood, urine, and bone mass measurement tests. Estrogen therapy should be considered on the basis of test results, together with the physician's and patient's judgement, and the assurance of appropriate follow-up.
- If the information indicates that the patient is not a likely candidate for osteoporosis, neither estrogen replacement therapy nor bone loss analysis is necessary. Appropriate follow-up is recommended to ensure that the information does not change over time.
- Women should be aware that the tests for measuring bone mass are complex, and subject to many potential sources of error. Only experienced facilities where physicians closely supervise their patients should be selected to perform measurements. To avoid costly and unneeded procedures, women should not take a bone mass measurement test on their own volition without a consulting physician's recommendation, or without being under a physician's supervision.

Nutrition/Exercise

The FDA Working Group on Osteoporosis identified nutrition and exercise as two of the key areas related to osteoporosis prevention. Osteoporosis is a multi-factorial disorder. Important non-dietary factors influence the risk for osteoporosis, including a person's age, sex, race, physical activity, stature, & hormonal status; but, nutrition and exercise are the only factors that can be controlled by the individual. More than any of the other measures that can be taken to reduce the risk of osteoporosis, nutrition

and exercise have received considerable media and consumer attention, and have been touted too often as singular and simplistic solutions to prevent fractures by building bone mass and stopping bone loss.

The prevention of osteoporosis in women at risk for this condition is a lifetime process. At different phases of her life, a woman will use different strategies to build bone mass and stop bone loss. Women and their physicians should work together to decide whether a woman is at risk for osteoporosis, what strategies are needed to reduce the risk of osteoporosis and the appropriate ages for using these strategies, and what types of monitoring and follow-up are needed to judge the effectiveness of prevention strategies. **Nutrition and exercise are two factors that women can control as they attempt to prevent osteoporosis.**

Nutrition as a strategy for preventing osteoporosis is primarily related to adequate calcium intake during active bone-forming years (approximately 10 to 35 years of age). Evaluating the calcium adequacy of the diet requires women to take an active role in becoming informed about sources of calcium, and ultimately in changing their diet to increase the level of calcium intake. It also requires women to become knowledgeable about the interaction between other nutrients and calcium (i.e., the "calcium depleters") and the limits of preventing osteoporosis through calcium intake. Women do have an active role to play in controlling the nutrition factor related to osteoporosis prevention. The most effective role will be played by women who work with their health care provider to develop a strategy that will work within the context of their individual life-styles.

Exercise is another factor related to osteoporosis prevention that women should know about, particularly the role exercise can play in the prevention of osteoporosis, and the types of exercises women at risk for osteoporosis should pursue.

Nutrition. The following are key educational messages about the role of nutrition in preventing osteoporosis.

- Calcium is a threshold nutrient, and deleterious effects in bone occur below a certain threshold.
- Osteoporosis is a multifactorial disorder, and inadequate calcium intake may be only one of a number of factors that may induce bone loss. It may be operative in some but not in other individuals.
- There is no doubt that calcium deficiency can induce osteoporosis in animal models; if calcium loss is greater than calcium absorption, calcium is withdrawn from bone and depletion occurs.

- The Recommended Daily Allowance (RDA) is set at 800 mg per day in the United States, but some studies suggest that this RDA is too low, and that bone loss may occur in some women unless intake is at least 1,000 mg per day for premenopausal, and 1,500 mg per day for postmenopausal women.
 - Surveys indicate that a majority of women in the United States do not achieve a dietary intake of even 800 mg of calcium per day from food sources.
 - Adults normally adapt to low calcium intake mainly by increasing the fraction of dietary calcium absorbed, but adaptation is impaired by menopause and by the aging process.
 - A daily intake of 1,000 mg of calcium per day is considered a desirable goal. This level of calcium intake can be achieved by dietary means alone, preferably from a diet that includes three servings of dairy products (preferably low-fat).
 - Children, adolescents, pregnant women, and individuals with osteoporosis or judged to be at increased risk of osteoporosis should consume from 1,200 to 1,500 mg of calcium per day.
 - Calcium supplements may be useful for individuals who cannot tolerate milk products, but education is needed on appropriate use of calcium supplements, side effects, forms in which they are best absorbed, and interactions with other medications.
 - Individuals who take, or intend to take, calcium supplements should seek the advice of their physician or pharmacist about which supplement is best for them.
 - Individuals who take calcium supplements should be knowledgeable about their benefits and risks, and should realize that taking more than 1,500 mg per day may be harmful to individuals predisposed to kidney stones.
 - When needed, calcium supplements should be taken during or after meals, when hydrochloric acid is more plentiful in the stomach.
 - While calcium carbonate and calcium phosphate have a relatively high content of elemental calcium per tablet, they are poorly absorbed in the absence of hydrochloric acid in the stomach.
 - The majority of bone in adult life is laid down during the relatively few years of the adolescent growth spurt, when bones grow in length, but bone continues to grow in mass during early adult life until about 35 years of age. Sufficient calcium must be available at this time for adequate peak bone mass to be achieved.
 - It is considered that insufficient accumulation of skeletal mass by young adulthood (at about age 18 to 25 years) appears to enhance the likelihood of fractures later in life, as age-related bone loss ensues.
 - Although most of the emphasis on prevention of osteoporosis has focused on retarding bone loss, efforts need to be made to increase peak bone mass.
 - **Three factors may be important in attainment of peak bone mass—heredity, nutrition, and exercise. Of these, only two factors can be changed.**
 - There is relatively strong indirect evidence that an increase in dietary calcium up to the recommended levels during puberty and up to about age 35 can increase peak bone mass. A threshold amount of calcium is needed to increase peak bone mass, and beyond that level, increasing calcium intake is of no benefit in terms of increasing peak bone mass.
 - There is less evidence concerning the role of exercise and peak bone mass.
- Exercise.** The key messages about the role of exercise in the prevention of osteoporosis are:
- A body of data has accumulated suggesting that an increase in weight-bearing physical activity (such as aerobic dancing and jogging) delays bone loss and, at least for the short term, increases bone mass. Although these data are encouraging, three caveats are:
 1. The rates of change in bone density may not be maintained for longer periods;
 2. Treatment and control groups have not always been randomly assigned, and therefore factors other than the effect of exercise may have been operating; and
 3. The amount of exercise required to achieve these rates requires rather intense weight-bearing exercise for 15 to 30 minutes a day several times a week, and this may not be appropriate for all women, some of whom may have other significant health problems (e.g., osteoarthritis of the knee or hip).
 - Women who exercise to the point of amenorrhea may become estrogen deficient and lose bone mass.
 - Women who are considering a routine exercise program should obtain a health evaluation from a health professional before undertaking any fitness program.

Prevention/Treatment

In focusing on various strategies for the prevention and treatment of postmenopausal osteoporosis, the

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FDA Working Group on Osteoporosis recognized that estrogens have a prominent role among currently available therapies in preventing or delaying postmenopausal bone loss. Long-term estrogen use presents both benefits and risks that should be thoroughly reviewed and discussed by women and their health care providers before estrogen use is started. In addition, a specific schedule for follow-ups should be established to regularly assess the impact of estrogen use on the health and well-being of the woman. Women should be advised of the possible side effects and adverse reactions that may be associated with estrogen use, instructed to monitor for these possible conditions, and strongly encouraged to report serious or unanticipated conditions that may be associated with estrogen use to their physician.

The Working Group also recognized that estrogen use may not be either the indicated therapy or the therapy of choice in women with postmenopausal osteoporosis. For this reason, it is important for women to know about the alternatives available to them, as well as the safety and effectiveness of these options.

The following are the primary health messages related to drug therapy for the prevention and treatment of postmenopausal osteoporosis:

- Women and their physicians are faced with the dilemma of using estrogen alone to prevent osteoporosis but increasing the risk of endometrial cancer, or combining estrogen and progestin to reduce this risk, but in turn, possibly blunting the protective effect of estrogens on heart disease. These benefits and risks need to be further evaluated before arriving at definitive recommendations for treating women with osteoporosis with hormone replacement therapy.
- **Under certain conditions, estrogen replacement therapy is of established benefit in preventing postmenopausal bone loss.**
- Soon after menopause, estrogen deficiency induces a transient phase of accelerated bone loss that calcium can not be expected to correct.

- Effectiveness of estrogen therapy is greatest when started near menopause, but continues up to 65 or 70 years of age.
- Estrogen replacement therapy may be associated with an increased risk of endometrial cancer.
- The majority of available studies do not suggest an association of estrogen therapy and breast cancer at any time. The evidence of this association is less clear after 20 years of estrogen use.
- Combining progestin with estrogen replacement therapy reduces the risk of endometrial cancer.
- The majority of evidence suggests that estrogen use has a protective effect against cardiovascular disease, but this is probably blunted by the concomitant use of progestin.
- Because of this effect on cardiovascular disease, overall mortality is decreased in women on estrogen therapy, even though the incidence of endometrial cancer is increased.
- Patient compliance is an important factor in long-term estrogen therapy. Educating women on the benefits of hormonal therapy on bone mass content, and documenting these changes, along with changes in life-style and exercise regimens, may make a positive impact on the health of climacteric women and their environment.

Management and Education

The FDA Working Group on Osteoporosis highlighted a number of issues, with a particularly significant impact on public health initiatives, to better inform and involve health care providers and women in the prevention and treatment of osteoporosis. A specific focus was given to the education needs of the older women (over 70 years of age), and questions were raised as to whether or not information from research findings on women under 70 can be applied to the prevention and treatment of osteoporosis in the woman of over 70 years. If not, what are the primary education messages that should be emphasized for women in the over-70 age category?

In addition to emphasizing the need to reassess the primary education messages particular to the over-70 woman, the Working Group also gave prominence to the importance of continued and consistent education messages directed to health care providers, women, and the public. It is especially important that education directed to encourage more public participation in changing high risk behaviors associated with osteoporosis be substantiated by a current and valid scientific base. This is also relevant for those education messages that are directed toward raising public awareness about this condition, and to influ-

ence consumers to act upon specific prevention strategies which require the intervention of, or consultation with, a health care provider.

Communication between women and their health care providers about the prevention, diagnosis, and treatment of osteoporosis is an enduring and interactive relationship. This relationship plays an essential role in the success of the individual in reducing the risk and severity of this condition. The degree to which health care providers involve women as partners in achieving improved skeletal health will be an influential factor in determining the degree to which women can change, and sustain more healthy life-style habits. The health care provider, together with the family and community-based organizations, establishes the incentives and support network necessary to receiving consistent encouragement, informed and effective intervention, and timely feedback.

While this panel addressed many of the unknown factors relating to the area of patient management and education, the important health messages that should be communicated to the public are:

- Although osteoporosis is considered to be a "female disease," men—especially over the age of 65-70—are also afflicted by the disease, but to a lesser extent.
- For many individuals osteoporosis is preventable, if women at risk are made aware of certain life-style changes before the disease begins.
- Particularly during the first three to four decades of life, ingesting adequate calcium, maintaining appropriate body weight, exercising, restricting alcohol, and avoiding cigarette smoking, are appropriate health strategies for the prevention of osteoporosis.
- Women of all ages need to ingest enough calcium so that they can absorb the amount of calcium their bodies require. Calcium absorption may decrease with age, so that the amount that must be ingested to supply the needs of the body may be greater for older women than that needed by younger women.
- The recommended levels of calcium (supplements or dietary sources) for adolescent girls, adult women, and older women range from 1,200 to 1,500 mg of calcium per day.
- For women over 70 years of age, the prevention of osteoporosis may be best measured in terms of the incidence of fractures—often precipitated by trauma or accidents—rather than by more traditional methods.
- For women over 70, the recommended treatment regime is the cautionary use of traditional treatments, plus more emphasis on strategies by which falls can be prevented, i.e., supportive footwear,

careful placement of rugs and furniture within the home environment, and proper use of medications.

- Women who reach the age of 70 after adhering to a regimen designed to prevent osteoporosis should continue that regimen.
- Factors other than bone mass which are important in increasing fracture incidence include frequency and intensity of trauma.
- Exercise that increases weight bearing by bones, but does not increase the risk of trauma (such as walking with proper footwear on pathways that provide secure footing) is important to the elderly of both sexes. Good muscle tone probably is also important in preventing trauma to bones.

Sources of Information

Research related to the prevention and treatment of osteoporosis has progressed significantly within the past decade, substantially advancing the public health community's understanding and knowledge about this debilitating condition. This research has established an important baseline of data on risk factors associated with osteoporosis, the life-style practices that will help to prevent this condition, and the role that such factors as nutrition, exercise, and estrogens play in the prevention and treatment of osteoporosis. The positive message from the research community is that women at risk can take active steps to change unhealthy life-style habits, adopt health habits for preventing osteoporosis, and pave the way for better health as they age.

The health care provider, public health educator, and health communicator all play a key role in providing women with the prevention messages related to osteoporosis. Research related to osteoporosis is evolving at a rapid pace, and the messages related to osteoporosis are often confusing and conflicting once they reach the marketplace. Therefore, it is particularly important that the research and medical communities clarify their findings about osteoporosis prevention, and that health care providers access timely, accurate, and current information as they work with women to apply the needed interventions appropriate at different phases of a woman's life. Physicians should be informed about the factors related to the prevention and treatment of osteoporosis, the interactions among these factors, and the sensitivities needed to assist women to constructively work through the physiological, psychological, and emotional outcomes associated with different life stages that may impede prevention strategies.

Information provided to the public and to primary care physicians can be confusing. The research com-

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munity and medical experts should clarify their messages on osteoporosis, its prevention and treatment. Physicians can serve as a focal point for providing women with timely and accurate information about osteoporosis prevention and treatment; therefore, they should be better informed about prevention and treatment interventions—especially about appropriate calcium and estrogen treatment programs for different patients.

The co-sponsors of the 1987 FDA Special Topic Conference are an excellent source of information about the prevention and treatment of osteoporosis for health care providers, public health educators, and health communicators. In addition, medical associations and professional societies should be encouraged to include osteoporosis as a priority topic for workshops and continuing education for health care providers—particularly since the science related to osteoporosis prevention will continue to focus public attention on this condition as research reveals new findings, and the population ages. The conference co-sponsors who develop and disseminate infor-

mation about osteoporosis prevention and treatment for both the public and health care providers are:

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Office of Consumer Affairs
Food and Drug Administration
Rockville, Maryland 20857
301-443-3170

Office of Disease Prevention and Health Promotion
U.S. Public Health Service
Washington, D.C. 20201
202-472-5660

National Institute on Aging
National Institutes of Health
Bethesda, Maryland 20205
301-496-4000

National Institute of Arthritis and Musculoskeletal
and Skin Diseases
National Institutes of Health
Bethesda, Maryland 20205
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National Institute of Diabetes and Digestive
and Kidney Diseases
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National Osteoporosis Foundation
Washington, D.C. 20006
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